K 131727

FEB 2 8 2014

510(k) Summary

In accordance with the requirements of 21 CFR.807.92, the following information about 510(k) safety and effectiveness is being submitted.

1. Submitter

CERAGEM Medisys Inc.
16 Jeongji1-gil, Seonggeo-eup, Seobuk-gu, Cheonan-si, Chungcheongnam-do, 331-833, Korea
Phone : (+82) 41-529-8422
Fax : (+82) 41-551-0767

2. Date Prepared

February 28, 2014

3. Device Name

Common name : CERA-CHEK 1070 Blood Glucose Monitoring System
Classification : Class II
(Regulation: 21 CFR § 862.1345)
Product Code : LFR, NBW(Blood Glucose Test System, Over the Counter), JJX, JQP

4. Predicate Device

CERA-CHEK 1070 Blood Glucose Monitoring System is substantially equivalent to Ascensia® CONTOUR ® Blood Glucose Monitoring System described as below.
(1) Device Name: Ascensia® CONTOUR ® Blood Glucose Monitoring System
(2) Manufacturer: Bayer HealthCare, LLC.
(3) 510(K) Number: K062058

5. Device Description

The CERA-CHEK 1070 Blood Glucose Monitoring System consists of the CERA-CHEK 1070 Glucose Test Meter, CERA-CHEK 1070 Blood Glucose Test Strips with Code Key, CERA-CHEK 1070 Control Solution 1 and Control Solution 2, a Lancing device, and CERA-CHEK Diabetes Management Software and cable needed for installing the software on the PC and for transmitting data from meter. Control Solution 1 and Control Solution 2 are required but not included with the meter. Control Solution 1 and Control Solution 2 are always

provided as a set. CERA-CHEK Diabetes Management Software and cable are required but not included with the meter. CERA-CHEK Diabetes Management Software and cable are always provided as a set.

6. Intended Use

The CERA-CHEK 1070 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, forearm, upper arm, palm, thigh, or calf. The CERA-CHEK 1070 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The CERA-CHEK 1070 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes controls. The CERA-CHEK 1070 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The CERA-CHEK 1070 Blood Glucose Test Strips are for use with the CERA-CHEK 1070 Blood Glucose Test Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, forearm, upper arm, palm, thigh, or calf.

The CERA-CHEK 1070 Control Solution is for use with the CERA-CHEK 1070 Blood Glucose Test Meter and Test strips as a quality control check to verify that the meter and test strips are working together properly and that the test is performing correctly.

The CERA-CHEK Diabetes Management Software is PC-based software intended for use in home and professional settings to help people with diabetes and their healthcare professionals in the review, analysis and evaluation of glucose results for effective diabetes management. It is intended for use as an accessory to compatible CERAGEM MEDISYS blood glucose monitoring systems. The CERA-CHEK Diabetes Management Software's language is English.

7. Comparison to Predicate Device

Comparison		
Item	**Device**	**Predicate**
Device Name	CERA-CHEK 1070	Ascensia® CONTOUR®
Similarities		
Detection Method	Amperometry	Amperometry
Enzyme	Glucose dehydrogenase (FAD-GDH)	Glucose dehydrogenase (FAD-GDH)
Test Time	5 seconds	5 seconds
Differences		
Coding	No coding	No coding
Memory	1000 blood glucose test results with date and time	480 blood glucose test results with date and time
Test range	20-600 mg/dL	10-600 mg/dL
Sample Volume	0.5 uL	0.6 uL
Humidity range	10-85%	10-93%
Temperature range	50-104°F 10-40°C	41~113°F 5-45°C
Power(Battery)	One 3-volt lithium battery (CR2032)	Two 3-volt lithium batteries (DL2032 or CR2032)
Level of QC	2 Levels (Control 1, Control 2)	3 Levels (Low, Normal, High)
Dimensions	94mm(H) x 53.6(W) x 14.9mm(T)	77mm(H) x 57mm(W) x 19mm(T)
Weight	40g	47.5g
Hematocrit range	10-70%	20-60%

Conclusion

As the comparison table, the CERA-CHEK 1070 Blood Glucose Monitoring System have same detection method, test range, and test time. Furthermore, the CERA-CHEK 1070 Blood Glucose Monitoring System is also using same enzyme and mediator. To sum up with the similarities, the CERA-CHEK 1070 Blood Glucose Monitoring System is similar with the predicate device because most of the specifications deciding the characteristic of the device are same. In conclusion, despite of the difference such as memory, coding, and etc, the CERA-CHEK 1070 Blood Glucose Monitoring System is substantially equivalent as compared to the predicate device.

8. Performance Characteristics

1. Analytical performance

A. Precision/Reproducibility

(1) Within-run Precision

Within-run precision was evaluated by analyzing venous whole blood samples spiked to five different glucose concentrations. The hematocrit of all samples was between 35 and 50%. Five different lot numbers of test strips and ten meters were used in the study and each of the samples was measured ten times per strip lot number per meter for a total of 100 measurements per glucose concentration. The samples were analyzed by one operator in one day.

Interval	1	2	3	4	5
Glucose concentration	30~50	51~110	111~150	151~250	251~400
YSI (mg/dL)	44	96	127	226	323
Mean	45.2	97.6	129.1	228.3	326.1
STD(mg/dL)	2.4	3.1	4.1	6.9	7.3
CV (%)	5.2	3.1	3.2	3.0	2.2

(2) Day to day precision

Day to day precision was evaluated by analyzing control samples at three different concentrations. Three lot numbers of test strips (one per glucose level) and ten meters were used in the study. Each of the control levels was measured once per day over twenty. Each of the control levels was measured once per strip lot number per meter. In total, 600 measurements were taken for each of the three levels. Results are summarized below:

Interval	1	2	3
Glucose concentration	30~50	96~144	280~420
YSI, mg/dL	43	108	304
Mean	42.6	108.4	303.8
STD(mg/dL)	2.3	3.4	8.6
CV(%)	5.5	3.2	2.8

B. Linearity/assay reportable range

The sponsor evaluated the linearity of the meter by preparing a series of 9 glucose samples, following the dilution scheme in CLSI EP6-A, and producing target values of 11, 52, 89, 157, 234, 310, 386, 461, 531, and 607 mg/dL.

Each of the ten levels was analyzed five times using three lots of test strips. All samples were also tested on the YSI 2300 analyzer. Linear regression of the data produced the following:

Strip Lot	Slope	Intercept	Corr Coeff (r^2)
1	0.9896	1.4433	0.9995
2	0.9786	2.4223	0.9997
3	0.9782	4.4741	0.9992

The results of the study support the sponsor's claimed glucose measurement range of 20 – 600 mg/dL.

C. Traceability, Stability, Expected values (controls, calibrators, or methods)

The CERA-CHEK 1070 Blood Glucose Monitoring System is traceable to the YSI 2300 Glucose analyzer which is calibrated using the YSI 2747 Glucose Standard which is a NIST traceable glucose standard.

Test strip shelf-life stability (closed vial) was assessed in an accelerated study with real time studies ongoing. The protocols and acceptance criteria were reviewed and found to be acceptable. The testing supported the claimed shelf life of 24 months when stored at 1- 32° C and 10-85% RH.

Test strip in-use stability (open vial) was assessed in real time studies. The protocols and acceptance criteria were reviewed and found to be acceptable. The testing supported the open vial stability of four months when stored at 1- 32° C and 10-85% RH.

Control shelf-life stability (closed vial) was assessed an accelerated study with real time studies ongoing. The protocols and acceptance criteria were reviewed and found to be acceptable. The testing supported the claimed shelf life of 12 months when stored at 1- 32° C and below 50% RH.

Control in-use stability (open vial) was assessed in real-time studies. The protocols and acceptance criteria were reviewed and found to be acceptable. The testing supported the open vial stability of four months when

stored at 1- 32° C and below 50% RH.••

D. Detection Limit

The measuring range of the device is 20 - 600 mg/dL. This range was validated by the linearity study.

E. Analytical specificity

The sponsor performed interference studies in accordance with CLSI EP7-A. Testing was performed in parallel (control samples vs. test samples) to minimize the effects of glucose metabolism. Whole blood was drawn into K3-EDTA anticoagulant tubes from healthy volunteers who were not on any medications. The glucose levels tested were 64, 151, and 257 mg/dL. The highest level was achieved by spiking. A low and high concentration of each potential interferent was then tested at each glucose level. The following substances were found not to interfere at the concentrations listed:

Substance	No interference up to:
Acetaminophen	6 mg/dL
Ascorbic acid	4 mg/dL
Dopamine	5 mg/dL
Ibuprofen	40 mg/dL
Metformin	4 mg/dL
Methyldopa	5 mg/dL
Salicylic acid	50 mg/dL
Uric acid	10 mg/dL
Bilirubin	4 mg/dL
Triglyceride	1,500 mg/dL
Cholesterol	500 mg/dL
Creatinine	10 mg/dL
Galactose	100 mg/dL
Gentisic acid	2 mg/dL
Glutathione	3 mg/dL
Hemoglobin	20 g/dL
L-dopa	4 mg/dL

Maltose	100 mg/dL
Sodium	150 mmol/L
Tolbutamide	64 mg/dL
Tolazamide	5 mg/dL
Xylose	10 mg/dL
Mannitol	800 mg/dL
Sorbitol	100 mg/dL
Xylitol	100 mg/dL
Lactitol	100 mg/dL
Isomalt	100 mg/dL
Maltitol	100 mg/dL
Hydrogenated starch hydrolysates	100 mg/dL

The sponsor has the following limitations in their labeling:

- High concentrations of dopamine, methyldopa, and Tolazamide may cause inaccurate test results
- Do not use during or soon after xylose absorption testing. Xylose (>10mg/dL) in the blood will cause interference.

2. Comparison studies

A. Method comparison with predicate device

For the user performance study, 200 participants collected and tested twice their own fingerstick sample in single measurements on the CERA-CHEK 1070 BGMS. The healthcare professional tested the collected samples of 200 participants and 20 contrived samples on CERA-CHEK 1070 BGMS. Within five minutes, fingerstick sample was collected from each participant by a healthcare professional for the system accuracy study and was tested on the YSI 2300 reference analyzer.

System Accuracy Study

Difference distribution for glucose concentration < 75mg/dL

	Technician	User
	Result	Result
within ±5mg/dL	77% (36/47)	55% (21/38)
within ±10mg/dL	89% (42/47)	87% (33/38)
within ±15mg/dL	100% (47/47)	100% (38/38)

Note: One contrived sample was <20 mg/dL and therefore not included in data analysis.

Difference(%) distribution for glucose concentration ≥ 75mg/dL

	Technician	User
	Result	Result
within ±5%	58% (100/171)	56% (91/162)
within ±10%	82% (140/171)	76% (123/162)
within ±15%	96% (164/171)	94% (152/162)
within ±20%	100% (171/171)	100% (162/162)

Note: One contrived sample was >600 mg/dL and therefore not included in data analysis.

Linear regression

	Slope (95% Confidence Interval)	Intercept (95% Confidence Interval)	Correlation coefficient
Technician vs YSI	1.0365 (1.0223~1.0507)	-5.5769 (-8.2708~-2.8831)	0.9948
User vs YSI	1.0322 (1.0117~1.0527)	-3.0441 (-6.4963~0.1081)	0.9901

B. Alternate Site Test

The study was performed with a total 100 volunteer's samples. Samples of alternative site were measured by volunteer and professional on the meter and were measured on reference analyzer.

Difference distribution for glucose concentration <75mg/dL

- Professional

	Palm capillary blood	Forearm capillary blood	Upper arm capillary blood	Thigh capillary blood	Calf capillary blood
within±5mg/dL	80%(4/5)	60%(3/5)	100%(5/5)	80%(4/5)	80%(4/5)
within±10mg/dL	100%(5/5)	100%(5/5)	100%(5/5)	80%(4/5)	100%(5/5)
within±15mg/dL	100%(5/5)	100%(5/5)	100%(5/5)	100%(5/5)	100%(5/5)

- lay user

	Palm capillary blood	Forearm capillary blood	Upper arm capillary blood	Thigh capillary blood	Calf capillary blood
within±5mg/dL	80%(4/5)	80%(4/5)	80%(4/5)	80%(4/5)	80%(4/5)
within±10mg/dL	100%(5/5)	100%(5/5)	100%(5/5)	100%(5/5)	100%(5/5)
within±15mg/dL	100%(5/5)	100%(5/5)	100%(5/5)	100%(5/5)	100%(5/5)

Difference distribution for glucose concentration ≥75mg/dL

- Professional

	Palm capillary blood	Forearm capillary blood	Upper arm capillary blood	Thigh capillary blood	Calf capillary blood
within±5%	73%(70/95)	59%(56/95)	65%(62/95)	66%(63/95)	64%(61/95)
within±10%	78%(74/95)	71%(67/95)	77%(73/95)	77%(73/95)	71%(67/95)
within±15%	93%(88/95)	95%(90/95)	95%(90/95)	97%(92/95)	98%(93/95)
within±20%	100%(95/95)	100%(95/95)	100%(95/95)	100%(95/95)	100%(95/95)

- Lay user

	Palm capillary blood	Forearm capillary blood	Upper arm capillary blood	Thigh capillary blood	Calf capillary blood
within±5%	62%(59/95)	62%(59/95)	64%(61/95)	65%(62/95)	57%(54/95)
within±10%	66%(63/95)	73%(69/95)	72%(68/95)	72%(68/95)	75%(71/95)
within±15%	94%(89/95)	93%(88/95)	96%(91/95)	94%(89/95)	97%(92/95)

within±20%	100%(95/95)	100%(95/95)	100%(95/95)	100%(95/95)	100%(95/95)

Linear regression and correlation coefficient.

- Professional

	Slope	Intercept	Correlation coefficient
	(95% confidence interval)		
Palm capillary vs YSI	1.0230	2.1615	0.9963
	(1.0054~1.0406)	(-1.4008~5.7239)	
Forearm capillary vs YSI	1.0519	-0.0445	0.9967
	(1.0347~1.0692)	(-3.5308~3.4419)	
Upper arm capillary vs YSI	1.0396	0.0729	0.9957
	(1.0202~1.0590)	(-3.8584~4.0043)	
Thigh capillary vs YSI	1.0303	0.5266	0.9957
	(1.0109~1.0496)	(-3.3818~4.4350)	
Calf capillary vs YSI	1.0364	0.7075	0.9945
	(1.0144~1.0583)	(-3.7344~5.1494)	

- Lay user

	Slope	Intercept	Correlation coefficient
	(95% confidence interval)		
Palm capillary vs YSI	1.0504	-1.5331	0.9955
	(1.0305~1.0704)	(-5.5767~2.5105)	
Forearm capillary vs YSI	1.0317	2.1956	0.9965
	(1.0143~1.0491)	(-1.3207~5.7120)	
Upper arm capillary vs YSI	1.0254	1.9080	0.9956
	(1.0059~1.0448)	(-2.0296~5.8455)	
Thigh capillary vs YSI	1.0405	-0.9615	0.9933
	(1.0163~1.0648)	(-5.8634~3.9404)	
Calf capillary vs YSI	1.0352	1.7561	0.9962
	(1.0170~1.0535)	(-1.9340~5.4461)	

3. Other Supportive Instrument Performance Characteristics Data Not Covered In the " Performance Characteristics" Section above

A. Hematocrit study

The effect of different hematocrit levels was evaluated using venous whole blood samples with hematocrit levels across the claimed range and altered to glucose concentrations from 21 – 529 mg/dL. There were five measurements for each combination of glucose concentration and hematocrit level. The results demonstrated that CERA-CHEK 1070 Blood Glucose Monitoring System produces accurate results over the claimed hematocrit range of 10 – 70%.

B. Altitude study

A study was conducted to evaluate the effect of altitude on the device. In this evaluation, venous blood at glucose concentrations of approximately 100, 200, and 300 mg/dL was tested using a decompression chamber to simulate the effects of altitude. Three lots of test strips and three meters were used. Each blood sample was also tested by the YSI 2300 analyzer. The meter readings obtained were compared to the YSI method and the percent bias was determined at each level against the YSI results. The results demonstrated that the CERA-CHEK 1070 Blood Glucose Monitoring System produces accurate results at altitudes up to 13,200 feet.

C. Temperature and humidity studies

In this study, three test strip lots were tested on three meters at three glucose concentrations (approximately 45, 120, and 300 mg/dL) at twelve combinations of temperature and humidity. Each combination of environmental conditions / glucose concentration / meter was tested in replicates of three. The temperatures tested ranged from a low of 10.0° C to a high of 41.2° C. The relative humidity tested ranged from 10.3% - 86.6%. Glucose concentrations were verified by the YSI reference method. The bias relative to the reference method was acceptable to support the claim that temperatures from 10 – 40° C (50 – 104° F) and relative humidity from 10 – 85% do not significantly affect the glucose results.

D. Infection Control Studies

The CERAGEM MEDISYS CERA-CHEK 1070 Blood Glucose Monitoring System is intended for single-patient use only. Disinfection efficacy studies were performed on the materials comprising the meter and lancing device by an outside commercial testing facility demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, CaviWipes (EPA Registration Number 46781-8). Robustness

studies were also performed by the sponsor demonstrating that there was no change in performance or external materials for the meter and lancing device after 1825 cleanings and 1825 disinfection steps with CaviWipes. The robustness studies were designed to simulate 5 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

E. Usability Study

A usability study was performed to assess the readability of the labeling by recruiting untrained lay users who were provided with the test kit and labeling. These lay users also completed a questionnaire regarding the clarity of the instructions and the ease of use of the device. The majority of the users responded that they understood the instructions and were able to successfully operate the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 28, 2014

CERAGEM MEDISYS, INC.
HAKSUNG KIM
3-2, JEONGCHON-RI, SEONGGEO-EUP, SEOBUK-GU, CHEONAN-SI,
CHUNGCHEONGNAM-DO 331-833
REPUBLIC OF KOREA

Re: K131727
Trade/Device Name: CERA-CHEK 1070 Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: LFR, NBW, JJX, JQP
Dated: January 06, 2014
Received: January 10, 2014

Dear Haksung Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k131727

Device Name: **CERA-CHEK 1070 Blood Glucose Monitoring System**

Indications for Use:

The CERA-CHEK 1070 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, forearm, upper arm, palm, thigh, or calf. The CERA-CHEK 1070 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The CERA-CHEK 1070 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes controls. The CERA-CHEK 1070 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The CERA-CHEK 1070 Blood Glucose Test Strips are for use with the CERA-CHEK 1070 Blood Glucose Test Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, forearm, upper arm, palm, thigh, or calf.

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The CERA-CHEK Diabetes Management Software is PC-based software intended for use in home and professional settings to help people with diabetes and their healthcare professionals in the review, analysis and evaluation of glucose results for effective diabetes management. It is intended for use as an accessory to compatible CERAGEM MEDISYS blood glucose monitoring systems. The CERA-CHEK Diabetes Management Software's language is English.

Prescription Use _____	And/Or	Over the Counter Use √ .
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Katherine Serrano -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k131727